

INFORMATION FOR THE UH RESEARCH COMMUNITY

Collaboration Corner

Education Update

Regulatory Binder | Sep. 30 | 9-10 am | Lakeside 1400

Investigator Initiated Studies- Refresher Course| Oct. 5 | 8-9 am | Lakeside 1400

For more information contact Deborah.Marko@uhhospitals.org

Certification Reminder

In order to meet federal criteria, UH requires training every two years for any person shipping or receiving biological or hazardous specimens. IATA/DOT training is conducted by the UH Department of Hospital Safety.

Quick Links

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[Research Compliance and Education Technology Management](#)

[William T. Dahms, MD Clinical Research Unit](#)

For questions, comments or suggestions, email clinicalresearch@uhhospitals.org

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Understanding Common IRB Stipulations

University Hospitals manages all human subject protocols electronically through iRIS™, the UHCMC IRB electronic submission system. Submitting a complete initial application results in fewer stipulations or required changes or clarifications to your application and thus reduces the time from submission to IRB approval. A list of common IRB stipulations cited by the IRB follows to help improve your initial application to the IRB.

To assist with using iRIS™, numerous [user manuals](#) can be found within the system by selecting the “Help” button on any screen; live training sessions are held monthly in Lakeside 1400 or by appointment. The manuals include screenshots providing a comprehensive way to navigate the iRIS™ submission process and troubleshoot difficulties. In addition, the “UHCMC IRB – iRIS™ Frequently Asked Questions,” document is on the Center for Clinical Research and Technology website, found [here](#).

Examples of IRB stipulations include:

“We received your response to stipulations but your revised application was not attached.”

While working in the Review Response Submission Form, when you finish editing your application, ensure the box in front of the listing for the revised application is checked and then select “Save Attachments”. This will attach your revised application to the packet that will be resubmitted to the IRB with your response. For further details, refer to Part 4 of the iRIS™ user manual.

“Your submission is missing department approval (via dept approval letter or iRIS signoff by department).”

For New protocols, amendments that increase risk and continuing reviews, departmental approval is required prior to IRB submission. Please refer to the UHCMC [IRB Policy Department Review of Protocols](#) or the iRIS™ [FAQ](#) sheet for further information. As each department manages approvals differently, please rely on your department review committee or department chair for obtaining proper departmental approval instructions.

“PI and those obtaining consent need to have current Human Subjects Protection certification.”

University Hospitals IRB requires [human subject protection certification](#) from all Principal Investigators, anyone who obtains consent from participants and for Key Personnel on NIH funded grants. This requirement applies to individuals who obtain consent. Researchers must complete the Basic course in the Collaborative Institutional Training Initiative (CITI) online training program to enter the Continuing Research Education (CREC) Program, administered through CWRU. The CREC Program is the human subjects protection certification program that UH and CWRU participate in. Following initial certification, participants are required to earn 12 CRECs every 3 years to renew their certification. Please follow this [link](#) for more information on both CITI training and the CREC program.

“For new studies, per the informed consent template, HIPAA language needs to be incorporated into the consent document.”

The IRB informed consent template contains the required language for HIPAA authorization; therefore a separate HIPAA authorization is not required. Please refer to the latest [template](#) when creating your informed consent document which includes all required elements. For assistance with creating your informed consent document please contact the IRB Administration at (216) 844-1529.

“A linking sheet and/or data collection form has not been provided.”

For chart review and similar studies, a data collection form must be provided to the IRB. This provides the IRB with detailed information regarding the data points that will be collected. Additionally, if participants' information will be de-identified, the IRB must be provided with an example linking sheet which shows how the participant will be connected with his/her study information.

“Because *NAME* is a non-UH employee that will have access to UH patient data/PHI, approval for this amendment can not be released until *NAME* has completed the UH research credentialing process. Please submit proof of credentialing completion to the UH IRB office and we can proceed with issuing approval for this submission.”

If you are adding a non-UH employee to a study who will be accessing UH protected health information (PHI), it is the principal investigator's responsibility to ensure they have completed the UH Research Credentialing process. Documentation of credentialing completion must be submitted to the IRB. Please be aware IRB approval for new studies or amendments will be withheld until documentation of credentialing has been provided. Additionally, if there are currently non-UH employees listed as investigators or study staff on an IRB approved protocol and they have not completed the credentialing process, the PI and study contact will be notified by the IRB upon review of the protocol. The PI will have 30 days to respond to the IRB as to the credentialing status by providing documentation or removing the non-credentialed individual from the submission. Please be aware non-UH employees are not authorized for access to UH PHI, and must discontinue all use of UH PHI until they have been properly credentialed. For questions about the Research Credentialing process please refer [here](#).